

THE FRANK R. LAUTENBERG CHEMICAL SAFETY FOR THE 21ST CENTURY ACT : *REQUIREMENTS AND EPA IMPLEMENTATION*

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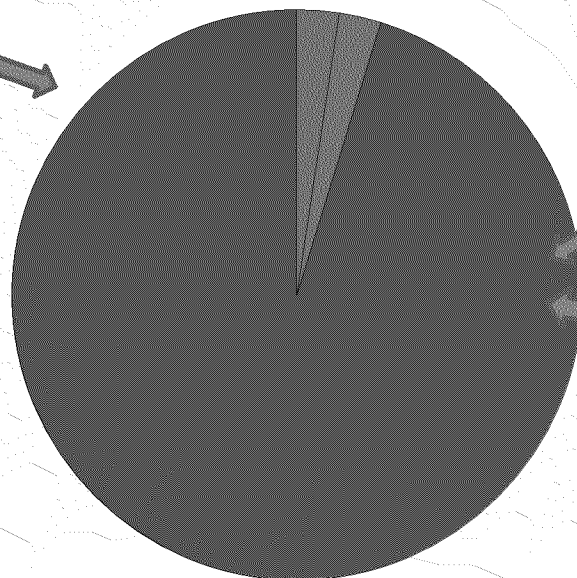
United States Chemical Regulation

Industrial Chemicals

~84,000 Chemicals
Reviewed & Regulated
under Toxic Substances
Control Act (TSCA)

By Office of Pollution,
Prevention, and Toxics
(OPPT)

- New Chemical Submissions do not require “new” data
- NEW mandate to assess existing chemicals



Pesticides

~2000 Chemicals (Active Ingredients)

Reviewed and Regulated
under FIFRA

By Office of Pesticides
(OPP)

FIFRA requires
experimental data

Food Additives, Drugs & Cosmetics

~2,000 AI

Federal Food, Drug, and
Cosmetic Act

By OPP & FDA

FFDCA requires
experimental data



TSCA Amended

The “Frank R. Lautenberg Chemical Safety for the 21st Century Act” was signed by the President and went into effect on June 22, 2016

Amends and updates the Toxic Substances Control Act of 1976

Passed by large bipartisan margins in the U.S. House (403 to 12) and unanimously in Senate

Received support from chemical industry and downstream users of chemicals, NGOs and other stakeholders



New Chemicals

Before a chemical can enter the market, EPA must make an affirmative determination that the chemical:

- *Presents* an unreasonable risk,
- *May present* an unreasonable risk,
- Is *not likely to present* an unreasonable risk, or that
- *Information is insufficient* to permit a reasoned evaluation of the risk.



Existing Chemicals: Prioritization

Establish a risk-based process to identify high- and low-priority substances:

High priority – the chemical may present an unreasonable risk of injury to health or the environment due to potential hazard and route of exposure, including risk to “potentially exposed or susceptible subpopulations”

Low priority – the chemical does not meet the standard for high-priority



Existing Chemicals: Risk Evaluation

- *High priority* designation triggers risk evaluation to be completed in 3 years
- For each risk evaluation completed, EPA must designate a new high-priority chemical
- Within 3 years, EPA must have 20 ongoing chemical risk evaluations
- Must consider risks to “potentially exposed or susceptible subpopulations,” including workers



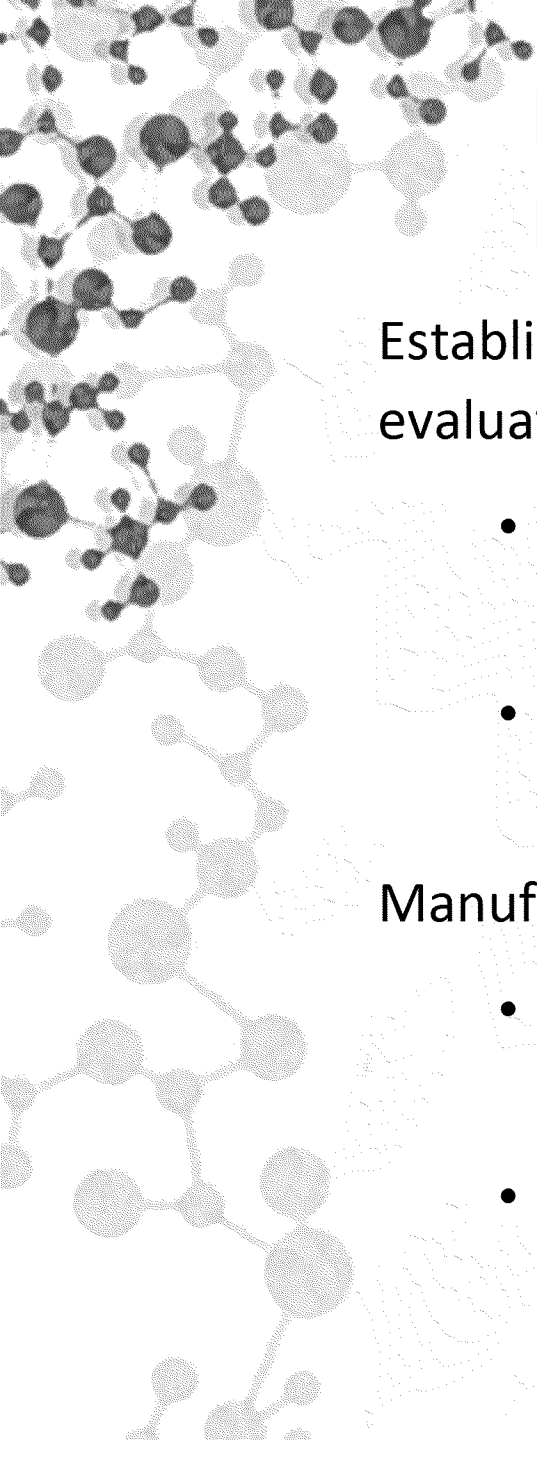
Existing Chemicals: Initial 10 Risk Evaluations

- EPA must identify a list of 10 chemicals from the 2014 Update to TSCA Work Plan and formally initiate risk evaluations by mid-December 2016
 - 2014 Update to TSCA Work Plan lists 90 chemical substances for assessment by EPA
 - Methodology was developed in 2012 and involves screening process for hazard, exposure, persistence and bioaccumulation
- Release the scope for each of the first 10 assessments by mid-June 2017



Existing Chemicals: Risk-Based Safety Standard

- Chemicals are evaluated against a new risk-based safety standard to determine whether a chemical use poses an “unreasonable risk”
 - The risk determination is to be made without consideration of costs or other non-risk factors
- Risks to “potentially exposed or susceptible subpopulations,” including workers, must be considered
- EPA must take risk management action in 2 years to address unreasonable risks



Existing Chemicals: Manufacturer- Requested Evaluations

Establishes a process for manufacturers to request that EPA evaluate specific chemicals, and pay costs as follows:

- For chemicals on the TSCA Workplan, manufacturers pay 50% of costs; and
- For all other chemicals, manufacturers pay 100% of costs

Manufacturer requests subject to the following limitations:

- Do not count toward the 20 risk evaluations EPA must have underway
- Administrator has discretion to grant manufacturer requests, but these requests must be 25% to 50% of ongoing reviews.



Existing Chemicals: Persistent, Bioaccumulative and Toxic Chemicals

- Fast-track process for certain PBT chemicals already on TSCA Workplan
- No risk evaluation; only a use and exposure assessment
- Rules to reduce exposure to the extent practicable must be proposed within 3 years of enactment and finalized 18 months later, unless a manufacturer requested a risk evaluation by Sept. 19, 2016
- Additional requirements encourage prioritization of other PBTs in overall risk evaluation process

❖ Status

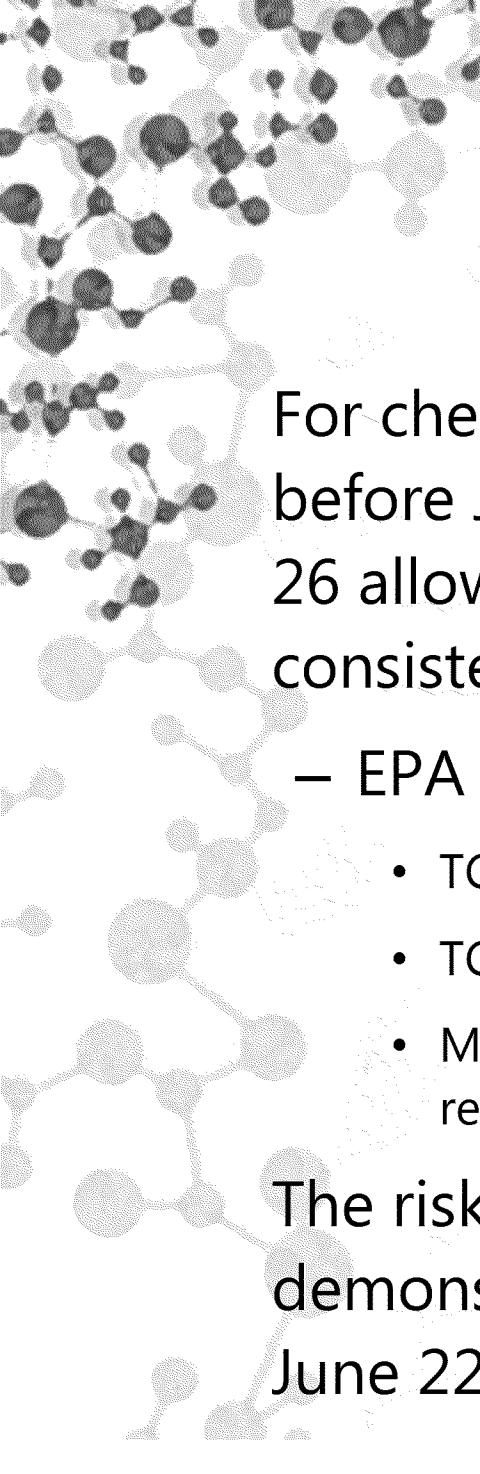
- 5 chemicals will get expedited action under TSCA 6(h)
- Manufacturer requests for risk evaluations were received for 2 PBT chemicals, which are thus excluded from the expedited action requirements



Existing Chemicals: TSCA Inventory

Industry must report on the chemicals they manufactured or processed in previous 10 years to determine if chemicals are currently “active” in the marketplace

- Chemicals will be designated as “active” or “inactive”
- No PMN required to move from “inactive” to “active”



Existing Chemicals: Ongoing Risk Management Rulemakings

For chemical uses with completed risk assessments before June 22, 2016 showing unreasonable risk, Section 26 allows EPA to propose and issue final Section 6 rules consistent with those assessments

- EPA anticipates issuing the following proposed rules:
 - TCE use in spot cleaning and aerosol degreasing
 - TCE use in vapor degreasing
 - Methylene chloride (MC) and N-methylpyrrolidone (NMP) in paint removers

The risk assessments for TCE, MC, and NMP all demonstrate significant risks and were finalized prior to June 22, 2016.



Existing Chemicals: Relationship to Other Federal Risk Management Authorities

If the Administrator finds that an action under non-TSCA authority can address an unreasonable risk identified under TSCA, certain procedures follow:

- Non-TSCA authority outside EPA: time-limited referral mechanism
- Non-TSCA authority inside EPA: either use the non-TSCA authority or make a discretionary finding that it is in the public interest to use TSCA



Testing Authority

New authority to issue *orders* to require testing, in addition to rulemaking authority, to speed the process of prioritization and risk evaluation.

- Must use tiered testing when possible.
- Must consider whether non-animal tests exist.

In 2 years, EPA must develop a strategic plan for promoting the development and implementation of alternative (non-animal) testing.



Confidential Business Information

Manufacturers must substantiate certain CBI claims including those for chemical identity (Chem ID) for existing chemicals

For new CBI claims, EPA must:

- Affirmatively review all chem ID CBI claims
- Screen a subset of non-chem ID CBI claims (25%)

For past CBI claims, EPA must retrospectively review past chem ID claims to determine if claims are adequately substantiated.

All CBI claims sunset after ten years unless reasserted by the company



Preservation of State Laws

Law does not prevent states from acting on chemical risks that EPA has NOT acted on.

If EPA does act, the following State actions are nonetheless preserved:

- Actions taken before April 2016
- The implementation of other environmental laws (air, water, waste treatment, disposal, reporting, monitoring, etc.)
- Co-enforcement of identical requirements and penalties that do not exceed the federal maximum
- Actions on chemicals identified as low-priority by EPA



Other New Requirements/Actions

Mercury Compounds and Inventory

- As required, EPA published in August 2016 an initial list of five mercury compounds prohibited from export after January 2020
- Requires that EPA publish an inventory of mercury supply, use and trade in the US
 - Must publish by April 1, 2017 and update every 3 years

Annual Report to Congress

Review Small Business definition within 180 days

Scientific Advisory Committee on Chemicals must be established by June 2017



Implementation

New Chemicals

- ✓ Review and make affirmative determination on PMNs and SNUNs
- ✓ Public Meeting 14 December 2016

CBI

- ✓ Review 100% of CBI claims for chemical identify & 25% of other claims

Section 6 Rulemakings on track for issuance in December/January.

Implementation

Initial Risk Evaluations

- ✓ Publish "First 10" – November 29, 2016
- Publish Scopes of "First 10" - June 2017

Final Prioritization Process Rule required by June 2017

- ✓ Draft proposal received by OMB November 7, 2016

Final Risk Evaluation Rule required by June 2017

- ✓ Draft proposal received by OMB November 11, 2016

Final Active/Inactive Inventory Reporting Rule required by June 2017

- Proposal planned for December 2016

Fees Rule (no statutory deadline)

- Proposal planned for January 2017

Science Advisory Committee established by June 2017

- ✓ FRN published to establish committee and solicit membership August 26, 2016

Implementation

Annual Plan for Risk Evaluations – publication required by January 2017 and annually thereafter

Additions to Mercury Inventory

- ✓ Published August, 2016

Mercury Inventory – to be published April 2017

Small Business Definitions –determine need for revision
December 2016 (included in proposed Inventory reporting rule)

Report to Congress – to be submitted December, 2016



Implementation: Longer-term deadlines

Mercury Use/Product Reporting Rule – June 2018

CBI Review/Substantiation Rule for Pre-Statute chemical identify claims – 1 year after publication of list of active chemicals

Guidance on Generic Names for CBI Chemicals – June 2018

Negotiated Rulemaking on Byproducts Reporting for CDR – June 2019

Alternative Test Methods Strategy – June 2018



For More Information

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>

Contact EPA at

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/forms/assessing-and-managing-chemicals-under-tsca>